

**REMARKS**

The Examiner makes several rejections and they are addressed in the order listed below.

- I. Claims 1-4, 6-19, and 22 are rejected under 35 USC § 112 ¶ 1 as allegedly failing to comply with the written description requirement.
- II. Claims 1, 2, 6, 7, 11-15, and 16 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by United States Patent No. 6,833,269 to Carpenter, as evidenced by Moretto et al., *J Neuropath Exp Neurol*, 53:78-85 (1994).
- III. Claims 1, 5, 8, 9, and 16-22 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kawasaki et al., *Neuron* 28:31-40 (2000).

**I. Claims 1-4, 6-19, and 22 Comply With The Written Description Requirement**

The Examiner states that:

With the exception of GDNF, the skilled artisan cannot envision the detailed chemical structure of the encompassed molecules, and therefore conception is not achieved until reduction to practice has occurred ...

*Office Action pg 3.* The Applicant disagrees. Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicant has amended Claims 1, 6, & 16 to recite "glial-derived neurotrophic factor". Claims 5 & 17 are, therefore, concomitantly canceled. These amendments are made not to acquiesce to the Examiner's argument but only to further the Applicant's business interests, better define one embodiment and expedite the prosecution of this application.

The Applicant respectfully requests that the present rejection be withdrawn.

## **II. Claims 1, 2, 6, 7, 11-15, and 16 Are Not Anticipated**

As the Examiner is well aware, a single reference must disclose each limitation of a claim in order for that reference to anticipate the claim. *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984). This criterion is not met with the Carpenter reference.

The Examiner states that:

... claims 1 and 2 are anticipated by ... [Carpenter] ... wherein hES are contacted with a soluble factor that is also expressed by fetal striatal astrocytes. ... The method for deriving TH<sup>+</sup> neurons comprises contacting hES with neurotrophin 3 and BDNF ...

*Office Action* pg 4. The Applicant disagrees. Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicant has amended Claims 1, 16, and 20 to recite that the human embryonic stem cell line is "co-cultured with fetal striatal cells".<sup>1</sup> Claims 3 & 11-15 are, therefore, concomitantly canceled. This amendment is made not to acquiesce to the Examiner's argument but only to further the Applicant's business interests, better define one embodiment and expedite the prosecution of this application.

The Applicant respectfully requests that the present rejection be withdrawn.

## **III. Claims 1, 5, 8, 9, and 16-22 Are Not *Prima Facie* Obvious Under Kawasaki et al.**

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference(s) themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488, 20 USPQ.2d 1438 (Fed. Cir. 1991); and MPEP § 2142; Establishing A Prima Facie Case Of Obviousness. The Examiner is reminded that if ONLY ONE of the above requirements is not met, then a *prima facie* case of obviousness does not exist. The Applicant submits that the Examiner's rejection does not meet these criterion. The Applicant rebuts the establishment of a *prima facie* case of obviousness by the argument below.<sup>2</sup>

The Examiner is respectfully requested to consider the argument below within the context of the claim amendments made above.

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<sup>1</sup> The Examiner has indicated that this represents allowable subject matter. *Office Action* pg 8.

<sup>2</sup> The Applicant notices that the Examiner refers to "anticipation" several times in this 35 USC 103(a) rejection (pg 6 & 7). The Applicant assumes this to be a "typographical error" and respond as if the term "obvious" was intended.

**A. Kawasaki et al. Provides No Motivation To Modify The Teachings**

The Examiner states that:

Kawasaki et al. teach that coculture with stromal cell line PA6 results in differentiation of ES into dopaminergic neurons ...

*Office Action, pg. 6.* The Applicant points out that Kawasaki et al. does not provide any suggestion to consider that co-cultures using non-stromal cell lines (i.e., for example, fetal striatal cells) might also induce differentiation of embryonic cells into dopaminergic neurons.

The Examiner further states that:

Kawasaki et al. further tested GDNF for possible effects on differentiation induced by the stromal cell line-derived factor (see page 36, final paragraph).

*Office Action, pg 6.* The Applicant disagrees because the Examiner has, apparently, not read the entire paragraph. The Applicant provides the full context below:

We have tested those factors that have been implicated in the regulation of dopaminergic differentiation ... such as ... GDNF ... So far, we have not observed any marked effects on the induction of dopaminergic neurons.

*Kawasaki et al. pg 36, last paragraph* [emphasis added]. Clearly, Kawasaki et al. admits failure in attempting to induce dopaminergic differentiation with glial-derived neurotrophic factor (GDNF). Kawasaki et al. does not provide any motivation to one having ordinary skill in the art to use GDNF. In fact, Kawasaki et al. provides a strong “teaching away” by stating that GDNF does not work.

The Applicant, therefore, respectfully requests the Examiner to withdraw the present rejection.

**B. Kawasaki et al. Does Not Teach All The Elements**

As already inferred from the above argument, Kawasaki et al. does not teach a human embryonic cell line co-cultured with fetal striatal cells.

**C. Kawasaki et al. Does Not Teach An Expectation Of Success**

The Examiner states that:

Kawasaki et al. further indicate that one of skill in the art would expect to use human ES cells with a reasonable expectation of success: “We infer that the same principles should be applicable to human cells ... (page 38, left column).

*Office Action, pg 7.* The Examiner has apparently not read the first part of this paragraph which clearly teaches that success using human cells is not yet to be expected:

Before ... ES cells can be applied to cell replacement therapy of Parkinsonism, important technical advances must be made at least in the following steps. First, we must test whether human ES cells differentiate into dopaminergic neurons in a manner similar to mouse ES cells.

*Kawasaki et al., page 38, left column, last paragraph* [emphasis added]. Clearly, the Examiner's conclusion that Kawasaki et al. teaches an expectation of success is not consistent with the actual opinion of Kawasaki et al. The Examiner is reminded that:

The expectation of success must come from the prior art and explicitly predict that the process recited in the claims would work.

*In re O'Farrell*, 853 F.2d 894, 7 USPQ2d 1673 (Fed. Cir. 1988) [emphasis added]. Not only does Kawasaki et al. not explicitly predict the success of using human cells, Kawasaki et al. explicitly states that the success of using human cells cannot even be commented upon.

Additionally, because Kawasaki et al. does not provide any teachings regarding non-stromal co-cultures with embryonic stem cells, there is also no explicit predictions that fetal striatal cells co-cultured with human embryonic stem cells would work.

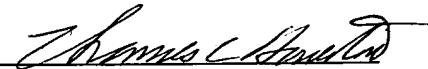
The Examiner is respectfully requested to withdraw the present rejection.

## **CONCLUSION**

The Applicant believes that the arguments and claim amendments make set forth above traverse the Examiner's rejections and make independent Claims 1, 16, & 20 novel and unobvious thereby making all associated dependent claims novel and unobvious. Therefore, the Applicant requests that all grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicant encourages the Examiner to call the undersigned collect at 617.984.0616.

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By:

  
Thomas C. Howerton  
Reg. No. 48,650

Medlen & Carroll, LLP  
101 Howard Street, Ste. 350  
San Francisco, CA 94105  
617-984-0616